

AMENDMENTS TO THE SPECIFICATION:

Please replace the paragraph at page 22, lines 8-16 of the specification with the following amended paragraph:

The compositions of the invention are particularly suitable as modalities for the treatment of any cladribine-responsive disease. Several disease states responsive to cladribine are well-documented in the literature (see *infra*). For any target disease state, an effective amount of the complex cladribine-cyclodextrin ~~complex~~ complex, i.e. the amorphous mixture of the optimized amorphous saturated cladribine-amorphous cyclodextrin complex with amorphous free cladribine as described above is used (e.g., an amount ~~effective~~ effective for the treatment of multiple sclerosis, rheumatoid arthritis, or leukemia).

Please replace the paragraph at page 23, lines 7-28, of the specification with the following amended paragraph:

Moreover, the route of administration for which the therapeutically effective dosages are taught in the literature should be taken into consideration. While the instant compositions optimize the bioavailability of cladribine following oral administration, it will be appreciated that even optimal bioavailability from oral dosage forms is not expected to approach bioavailability ~~obtain~~ obtained after intravenous administration, particularly at early time points. Thus, it is often appropriate to increase a dosage suggested for intravenous administration to arrive at a suitable dosage for incorporation into a solid oral dosage form. At the present time, it is envisioned that, for the treatment of multiple sclerosis, 10 mg of cladribine in the instant complex cladribine-cyclodextrin complex in the instant solid dosage form would be administered once per day for a period of five to seven days in the first month, repeated for another period of five to seven days in the second month, followed by ten months of no treatment. Alternatively the patient would

be treated with 10 mg of cladribine in the instant complex cladribine-cyclodextrin complex in the instant dosage form once per day for a period of five to seven days per month for a total of six months, followed by eighteen months of no treatment. ~~For further dosing information, see also U.S.~~

~~Provisional Patent~~

~~Application No. [[_____]] [IVAX0021-P-~~

~~USA/Attorney Docket No. 033935-011], and U.S. Provisional Patent~~

~~Application No. [[_____]] [IVAX0022-P USA/Attorney Docket No. 033935-012], both entitled "Cladribine Regimen for Treating Multiple Sclerosis", both filed on March 25, 2004 and incorporated by reference herein in their entireties.~~